PHYSICAL PROPERTIES OF ACUPUNCTURE NEEDLES: DO DISPOSABLE ACUPUNCTURE NEEDLES BREAK WITH NORMAL USE?

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A manuscript submitted to the faculty of the
Orofacial Pain Graduate Program
Naval Postgraduate Dental School
Uniformed Services University of the Health Sciences
in partial fulfilment of the requirements for the degree of
Master of Science
in Oral Biology

June 2016

Naval Postgraduate Dental School
Uniformed Services University of the Health Sciences
Bethesda, Maryland

CERTIFICATE OF APPROVAL

MASTER'S THESIS

This is to certify that the Master's Manuscript of

James Kyle Vick

has been approved by the Examining Committee for the thesis requirement for the Master of Science degree in Oral Biology at the June 2016 graduation.

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ACKNOWLEDGEMENTS

Special Thanks To:

- LCDR Ling Ye
- CAPT Steve Hargitai
- CAPT (retired) John Johnson
- CDR (retired) Lisa Sharp
- Mr. Clinton Coates – research librarian
- Dr. Dan Brooks – biostatistician

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June 2016

NAVAL POSTGRADUATE DENTAL SCHOOL
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2016

This manuscript is written to be submitted for publication to the MEDICAL ACUPUNCTURE JOURNAL. Guidelines can be found at http://www.liebertpub.com/forauthors/medical-acupuncture/233/

MANUSCRIPT FOR SUMISSION TO THE MEDICAL ACUPUNCTURE JOURNAL

PHYSICAL PROPERTIES OF ACUPUNCTURE NEEDLES: DO DISPOSABLE ACUPUNCTURE NEEDLES BREAK WITH NORMAL USE?

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MANUSCRIPT FOR SUMISSION TO MEDICAL ACUPUNCTURE JOURNAL

PHYSICAL PROPERTIES OF ACUPUNCTURE NEEDLES: DO DISPOSABLE ACUPUNCTURE NEEDLES BREAK WITH NORMAL USE?

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GUIDELINE II: ABSTRACT

INTRODUCTION:
Although literature suggests acupuncture is a safe therapeutic intervention, and failure of disposable acupuncture needles is considered rare, recent case reports indicated that re-use or over-use of these needles could lead to needle failure and increased health risk.

OBJECTIVE:
The objective of this study is to test the potential for breakage of three brands of disposable acupuncture needles.

METHOD:
Three brands (30 needles per brand) of commonly used single-use disposable acupuncture needles were imaged using digital microscopy (Hirox KH-7700, Digital Microscope and software) to visually evaluate for manufacturing defects. Lamb shank, which has complexity of tendon, fascia, and bone, was used to mimic human tissue. The needles (n=10) were stressed in the tissue substitute under three successively more demanding testing protocols. Two of the protocols simulated clinical use and a third simulated over-use. The needles were re-imaged after stressing and visually assessed.

RESULTS:
Only one manufacturing scuff mark was noted out of 90 needles before stress testing. Needles buckled but did not break when they were stressed beyond normal clinical use. No cracks or fractures were noted after stress testing.

CONCLUSION:
Stressing disposable acupuncture needles within clinical practice norms did not lead to needle breakage. Simulated over-use of acupuncture needles did not lead to work-hardening and breakage.

GUIDELINE III: KEYWORDS

Key words: broken needle, disposable needle, acupuncture safety, needle properties

GUIDELINE IV: MANUSCRIPT

CHAPTER 1: INTRODUCTION AND LITERATURE REVIEW

Broken acupuncture needles are rarely documented, and yet there are case reports proving this does occur. The origins of acupuncture are Chinese, however, there are many different types of needle therapy. Acupuncturists in Japan historically practiced a style of needle therapy in which short sections of needle were permanently implanted called Maibotsu-Shin. The current recommended use of acupuncture needles is for needles to not stay in treated tissues for any extended length of time.[1] Any part or remnant of these short sections of needles remaining in the tissues have the risk of migrating to vital organs and may require surgical removal.[2]

Acupuncture safety and clinical procedural guidelines have been well researched.[1,3,4,5,6,7] The physical properties of acupuncture needles have not been as extensively studied. Recent research on needle properties suggests a wide variation in the quality of needles. The use of inferior materials or poorly manufactured needles could contribute to more frequent needle breakage.

The practice of acupuncture has received ongoing research attention concerning safety. Since recognition of the germ theory beginning in the early 19th century medical providers have known of the need to sterilize instruments to avoid cross infection. Acupuncture needles were sterilized and reused for the majority of the last 100 years. In 1978, an outbreak of hepatitis in the United Kingdom occurred because of lapses in sterilization protocols.[8] This event was a

driving force in the development of disposable acupuncture needles.[8] In 1986, a bovine spongiform encephalopathy (BSE), or mad cow disease, outbreak led to a change in the standard of care. The only safe alternative was disposable needles, as autoclaving could not assuredly destroy the prions that transferred the disease.[9] The use of disposable needles is now considered the standard of care by the World Health Organization (WHO).[1]

A literature review of acupuncture needle safety identified numerous studies. The vast majority of the articles reviewed did not report broken needles as a relevant finding. In a 2004 study of adverse acupuncture events, Endres surveyed over 190,000 patients and totaled 1.77 million therapy sessions. He reported an occurrence of 2.4 adverse events per 10,000 patients, of which one broken needle was reported.[3] White completed a comprehensive review of literature, case reports, and population surveys from 1994 to 2003. He found a ratio of 0.55 adverse events per 10,000 patients. In White's article, two broken needles were reported.[5] Witt's 2009 article found a higher incidence of adverse events than other similar analyses. He concluded from his observational study of 229,230 patients that 2.2% of those patients reported adverse events required further treatment, including two reports of broken needles.[6] Fifteen cases of broken needles were reported by He et. al. in a 2012 systematic review covering the years from 1956 to 2010.[4] Considering the time period researched in this article, it is reasonable to expect that both disposable and re-usable needles were reported as broken. A 2015 systematic review of case reports from China between 1980 and 2013, Wu et. al. reported three cases of broken

needles.[7]Considering the frequency with which acupuncture is performed throughout the world and the body of evidence supporting safety, needle breakage is a rare occurrence. However rare the occurrence of broken acupuncture needles may be, one cannot rule out the potential for significant harm when it does.

Research on the physical characteristics of acupuncture needles is a fairly recent phenomenon. Hayhoe in a 2002 report suggested economic pressures to produce cheaper disposable needles might be driving manufacturers' to take short cuts in production. His report also suggested that reports of needle fractures might be due to microscopic faults, which allow fractures to occur after manual or electric manipulation or muscular contraction. His findings indicated problems were associated with the form of the needle tips.[10] Xie recently examined disposable acupuncture needles using a scanning electron microscope (SEM). His paper reported some of the same needle tip faults as Hayhoe and called on manufacturers, to review quality control procedures.[11] In 2014, Zhang tested the buckling characteristics of various disposable acupuncture needles. His research concluded that plastic handled needles did not buckle as easily as copper wound handles. He suggested this characteristic could have an impact on the fatiguing characteristic of one needle as compared to another.[12] With evidence to support real, albeit rare, occurrences of broken needles, it is interesting to note that more testing of the physical properties of disposable needles has not been published.

If Hayhoe's and Xie's hypothesis is correct, and manufacturers are cutting

corners and making an inferior product, the next logical inquiry would be to investigate whether needle fatigue or fracture occurs with normal clinical use. To understand what might be happening clinically when needle breakage occurs, it is necessary to review available case reports. Lewek et. al. in 2012 published a single case report of a broken needle along with a summary of broken acupuncture needles reported in the literature by using the search terms “foreign bodies, needle, acupuncture” on PUBMED.[13] A similar search was made for this study on March 15, 2016 which found twenty-seven case reports using Lewek’s PUBMED search words. After reviewing the case reports, fifteen were excluded for various reasons including: self-harm, ingestion of needles, purposeful implantation of needles (Maibotsu-Shin), or the date of acupuncture treatment predating the commercial availability of disposable acupuncture needles in 1978. Three cases were excluded because of an inability to determine if the needles were broken or purposefully implanted. Seven cases were considered appropriate for inclusion.[14,15,16,17,18,19,20] The majority of these seven case reports gave no definitive reason for the needle failure. Some of the explanations offered included inexperienced or untrained practitioners, self-administered acupuncture with work-hardening of the needle, and stuck needles that were forcibly removed.

The purpose of this study was to determine whether acupuncture needles break when used in accordance with (WHO) recommendations and established standards of care. The intent was to physically test disposable acupuncture needles within a realistic model to ascertain if needle breakage was possible when simulating clinical use or over-use.

CHAPTER 2: METHODS AND MATERIALS

Disposable acupuncture needles were stressed in a way that resembled light clinical use (test 1), moderate clinical use (test 2), and then gross over-use with poor needling technique (test 3). Guidance for the use of acupuncture needles in the testing protocol was taken from the WHO - Guidelines on Basic Training and Safety in Acupuncture.[1]

A lamb shank was selected as the testing substrate for this study. Synthetic tissues have been used in other studies[11] but are too simplistic and do not mimic human tissue since they do not have muscle, fascia or bone. They also deposit a sticky, oily residue on the acupuncture needles that is difficult to remove before viewing under a microscope[11].

Due to lack of preliminary data or a similar study to generate standard deviation for the power analysis, a sample size of 10 for each test was selected based on Xie et. al. 2014 SEM study.[11] A total of 90 needles were imaged in a minimum of three places before physically testing them. The 90 needles were each re-imaged after testing in the same three or more areas. Three commercial brands of acupuncture needles were chosen from a common supply house Lhasa OMS, Inc. The needle brands and manufacturers included:

- Brand A: Seirin brand needles manufactured by Seirin Corporation - Shizuoka, Japan,
- Brand B: Hwa-to brand needles manufactured by Suzhou Medical Appliance Factory, Suzhou, China
- Brand C: Hua Xia brand needles manufactured by Suzhou Medical

Appliance Factory, Suzhou, China

The needle size tested was #5 needles, 0.25mm (diameter) x 40mm (length) w/ insertion tubes. All three brands of needles had metal wire wound handles.

The 90 needles were initially assessed through a Hirox digital microscope at 50x magnification and photographs were taken in key stress areas.(see figure 1) The Model KH-7700 microscope was manufactured by Hirox-USA Inc. Hackensack, New Jersey USA. The examiner recorded any manufacturing defects such as surface scuff marks, cracks, or narrowing of needle shaft diameter before the needles were stressed.

Test 1 (light clinical use)

In the first test, the insertion tube guide was used. The needle was tapped into the tissue. The insertion tube was removed. The needle was then inserted to 75% shaft length and then withdrawn to within a few millimeters of the tip in a vertical in and out manner for 20 repetitions. This process was completed without redirection of the needle. Once 20 repetitions were completed the needle was withdrawn, disinfected and examined under the Hirox microscope.

Test 2 (moderate clinical use)

The parameters for the second test were similar to the first test. An insertion tube was used to insert the needles and then the tube was removed. The needle was inserted at a 45-degree angle from the surface of the tissue to a

depth of 75% of the needle shaft length and withdrawn as before with an in and out manner for 5 strokes. The needle was then redirected after every five strokes. The directionality of the needle insertions was as follows: 5 insertions in a superior direction, redirect and 5 insertions in an inferior direction, redirect and 5 insertions were made to the right; redirect and 5 insertions were made to the left, for a total of 20 insertions. (See Figure 2) Once 20 repetitions with redirection were completed the needle was withdrawn, disinfected and examined under microscope.

Test 3 (gross over-use with poor needling technique)

The third test was intended to simulate over-use and mechanical fatigue of the disposable needles, possibly to failure. The insertion guide tube was not used. The needle was inserted into the tissue from the handle only to 75-100% of the shaft length and then withdrawn to within a few millimeters of the tip for 100 repetitions. Redirection was attempted with every insertion. The goal was to engage bone and fascia as often as possible.

All of the brands of needles were re-examined, imaged, and findings recorded. The examiner was looking for signs of fatigue such as cracks along the needles shaft and buckling or any irregularities of interest were recorded. Any areas warranting further inquiry was viewed at a more powerful magnification of 100X - 150X for further evaluation.

The following control conditions were set to maximize uniformity in testing:

1. The lamb shank was tested at room temperature.

2. The needles were manipulated using only the handles according to WHO clinical safety protocols.[1] At no time were the needles manipulated by touching the needle shaft.

4. A permanent marker was used to mark each needle at 75% length to insure accuracy of depth of insertion accuracy. The WHO Guidelines for acupuncture safety state," The junction between the handle and the shaft is the part that is apt to break. Therefore, in inserting the needle, one-quarter to one-third of the shaft should be kept above the skin."[1]

5. Needles were disinfected and wiped with CaviWipes brand disinfectant after use on lamb shank, per CaviWipes manufacturer instructions. CaviWipes is manufactured by Metrex Research LLC., Orange, California USA.

6. Paper labels were attached to each needle handle with waxed thread to identify the brand and test protocol each needle was assigned to. This allowed the labels to be removed for testing and then reattached to facilitated identification and organization of the needles after experimentation.

CHAPTER 3: RESULTS

Observations before stress testing found Brand A Needles (Seirin) to appear more polished and to have sharper looking, more centered tips compared to brand B (Hwa-to) and C (Hua Xia). Seirin needles had more consistently wound and finished handles. Hwa-to and Hua Xia needles often had less sharp looking tips and these tips were often not perfectly centered on the needle (See photograph A). Handles on the Hwa-to and Hua Xia needles were not consistently finished, and often had rough looking edges where their handle windings stopped at the junction of the handle and shaft (See photograph B). Although there were numerous minute scuff marks located on the shafts of all the needles imaged, only one major surface scuff mark was noted in a single Hwa-to needle. This scuff mark was 4-5x larger than other smaller marks and was documented at a higher resolution in pre-stress imaging where it appeared to be a rough area on the surface of the needle shaft (See photograph C). This particular needle was stressed in test 2 after which the scuff mark was not evident. This suggests the scuff mark was some superficial stain or blemish, which was rubbed off during the insertions into the lamb shank or with CaviWipes during disinfection.

Analysis of test 1 revealed there was no visible impact on the integrity of the needles in any of the three brands. Imaging of these needles is indistinguishable between pre and post testing (data not shown). Test 2 resulted in minor buckling of two needles out of thirty mid-shaft only. The areas buckled at no more than a 5

degree angle. The only difference between testing protocol 1 and 2 was redirection of the needles. Imaging of the needles stressed in test 2 showed no fractures or surface irregularities. Test 3 most often resulted in buckled areas on the mid-shaft of the needles or the junction between shaft and handle. When two buckled areas were created the needles often formed a “dog leg” shape, with a bend at the handle and mid shaft. (See photograph D) Buckled areas were bent in a range between 5 and 40 degrees. The main differences between test 3 and the previous tests were the initial insertion without a guide tube and the number of insertions and direction changes. Imaging of the needles stressed in test 3 showed no surface changes, such as fractures or abrasions, compared to unstressed needles. None of the needles tested in any of the three protocols was broken.

CHAPTER 4: DISCUSSION

Test 1 did not generate any buckling on needles from all three brands. Test 2 resulted in buckling of only two needles. Good clinical practice would suggest minor bucking of needles in test 2 would have necessitated those needles being discarded from further use. Various hypotheses for the cause of needle breakage in published case reports included: work hardening through over-use of the needle, poor needling technique as a contributor, or a manufacturing defect in a section of the needle. The basis for test 3 came from a 2010 case report published by Miyamoto S. involving a patient who performed self-acupuncture to his occipital area every evening for neck pain. Eventually the needle work-hardened and a portion of the needle broke off in this area and migrated to the medulla, necessitating surgical removal.[20] Test 3 attempted to replicate an over-use scenario with the anticipated result of work-hardening of an acupuncture needle until it fractured. Excessive careless force used for insertion or redirection seemed to increase the chance of buckling. The experience of the provider would possibly mitigate this occurrence but the test was meant to simulate poor technique. Test 3 showed more needle buckling in comparison with test 2, however no broken needles from test 3. (See photograph H)

There were several limitations discovered while conducting this study. The possibility exists that resolutions ranging from 50X to 150X to image the needles in a Hirox microscope may have been too low of a magnification to view minute defects in the tip, shaft, or handle of the needles. However, test 3 was sufficiently strenuous that any significant defect along the length of the needles was

expected to result in breakage. Xie and Hayoe both looked at acupuncture needles at 5000x magnification in a SEM. A human red blood cell appears fairly detailed at 1000x magnification, which prompts some reservation concerning the clinical significance of any defects noted at 5000x magnification. Using a Hirox microscope at 50X – 150X, any surface abnormalities that might predispose a needle to breakage would most likely be evident.

Most of the needles in this study came from the same lot number so variation in materials and manufacturing process may be a confounder. Hwa-to and Hua Xia needles were produced by the same manufacturer. Future studies should Increase the number of needles imaged, the number of manufacturing lots, and the number of different manufactures. These changes may find a fault in the needles, which might predispose the needle to failure.

The Hwa-to (brand B) and Hua-xia (brand C) needles had the same copper wound handle. The Seirin (brand A) needles were wound with a silver-colored alloy wire on their handles. Handle differences made complete blinding impossible. In future testing the use of 2mm black heat-shrink tubing, which is commonly used in electronics, could be used to hide the handles and blind the needle brand completely; however this may stiffen the handles and make test results inaccurate.

Synthetic tissue models also come in several different consistencies, which could create confusion regarding model validity. One model may be too stiff and another too soft compared to human tissue composed of skin, fascia, muscle and bone. The chosen animal tissue model performed well as a

substitute for human tissues. Several of the synthetic tissue models considered for this study did not have a realistic “feel” as they were being needled, as there was more resistance during needle insertion and withdrawal. The lamb shank gave a very similar “needle feedback” to human tissue receiving needle therapy. (See photograph E)

One quoted study discussed a comparison between plastic handled needles and needles with a copper wound handle[12]. Their conclusion was plastic handled needles buckle less easily than copper wound handled needles. The current study did not include plastic handled needles in testing. Stiffer handles may have the potential to focus more fatiguing stresses on the interface between the shaft of the needle and the handle. This comparison would be an interesting addition to further research.

We were specifically interested in disposable acupuncture needles. Much of the available research reviewed was accomplished during years that overlap the common use of both disposable and re-usable needles. Though today the standard of care requires disposable needle use, the possibility of a re-usable acupuncture needle currently being in use cannot totally be ruled out. Malpractice in many forms could still occur despite clear acceptable guidelines for care.

The failing point of acupuncture needles should be well beyond the demands of clinical practice. Work hardening of a needle shaft and eventual fracture is a natural course that can be mitigated with the re-use or over-use of a single-use disposable needle. The most concerning etiology of needle breakage is that which might occur with the initial few insertions, which would most likely be

caused by a manufacturing defect. Manufacturing defects are possible although not proven in this study. Prudent practice would include visual inspection of any needle prior to insertion. Comparison of a needle after being withdrawn side by side to a needle that has not been used would enable immediate recognition of any needle tip broken or left in tissues. If needle breakage is found, referral for imaging and consultation regarding surgical intervention should be considered. Re-use of disposable needles is never an acceptable practice. Needles, which might buckle during use, should not be further used and should be discarded. Never insert a needle past 75% of its length so that if breaks there is sufficient needle exposed to facilitate removal. Needles should be inserted slowly and redirected gently to avoid buckling.

In future publications of case reports involving breakage of acupuncture needles, documentation of the needle characteristics such as: brand, length, diameter, lot number and circumstances surrounding the occurrence should be gathered. This minimum information would shed much needed light onto this rare but potentially serious event. As collection of data stands now, comparisons of case reports in a meaningful way are very difficult.

CHAPTER 5: CONCLUSIONS

Case reports of needles breaking are rare. None of the tested needles broke in this study. Needle buckling was not observed in the test which simulated clinical use without redirection before insertion. When needles were redirected with good technique, needle buckling rarely occurred. Test 3 resulted in significant needle buckling. This buckling did not seem to have a relationship to the type of needle but instead the manner in which the needle was used. Although this study was unable to reproduce needle fracture, work hardening would seem the most likely etiology leading to needle breakage.

In summary, the tested acupuncture needles resisted fatigue and failure in a test meant to simulate clinical use. Adverse events in clinical acupuncture related to the mechanical properties of needles appear to be low.

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GUIDELINE V: LIST OF FIGURES

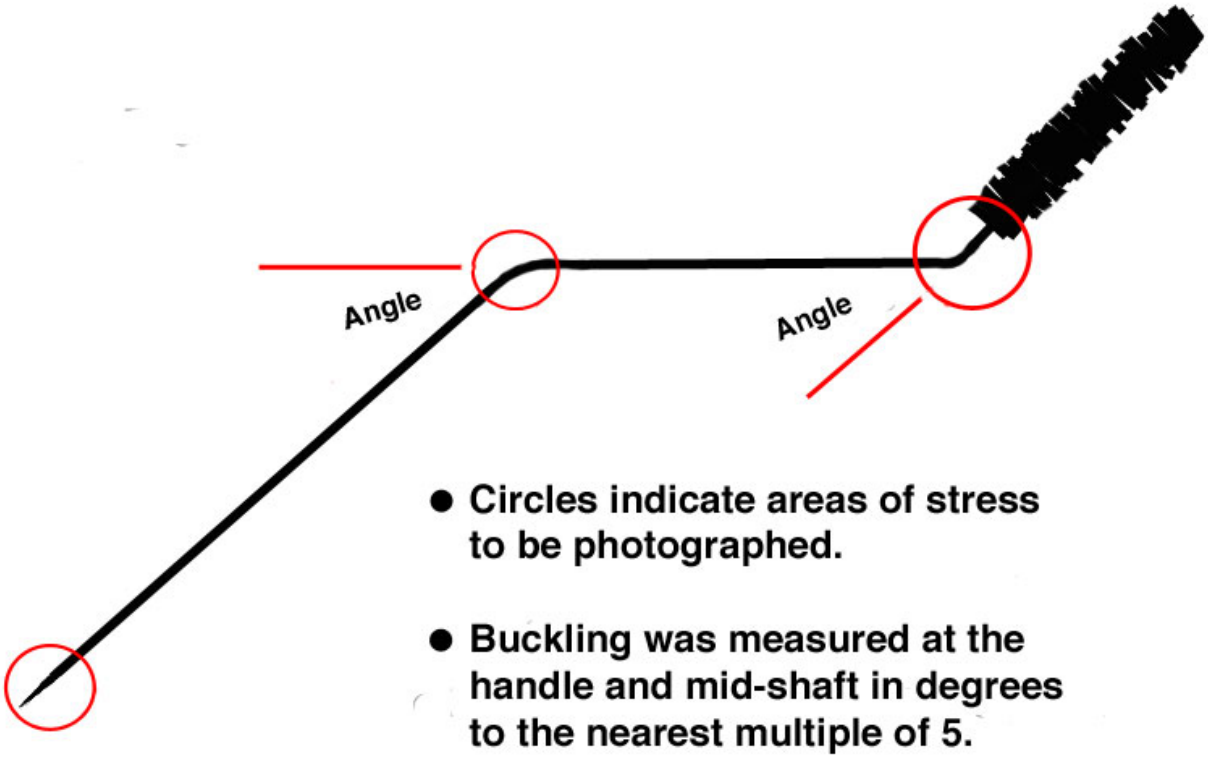


Figure 1

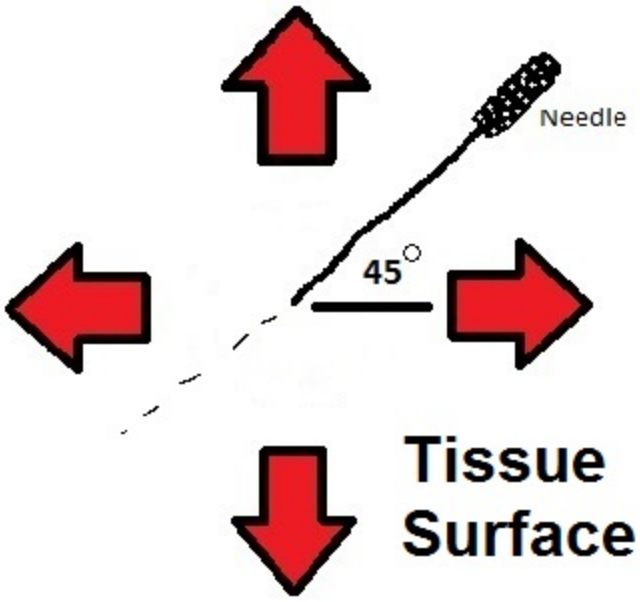
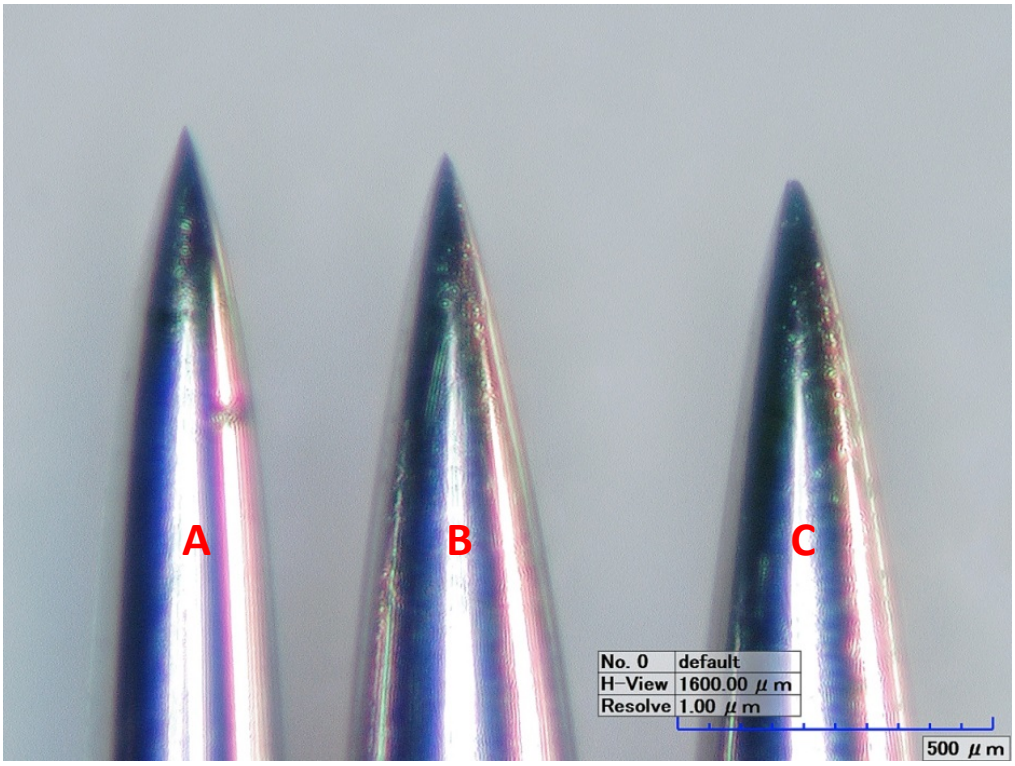
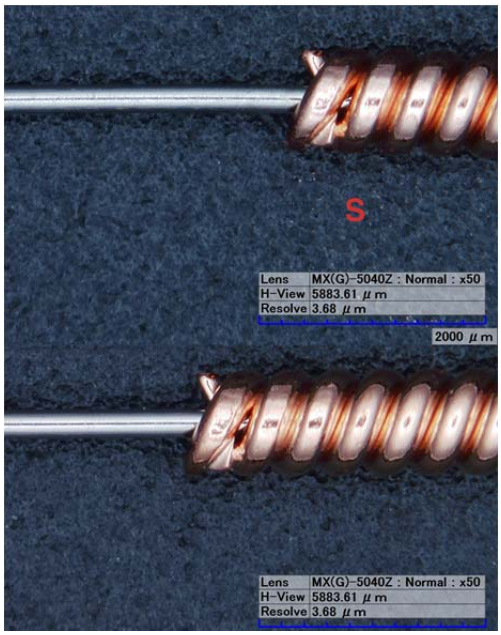


Figure 2



Photograph A



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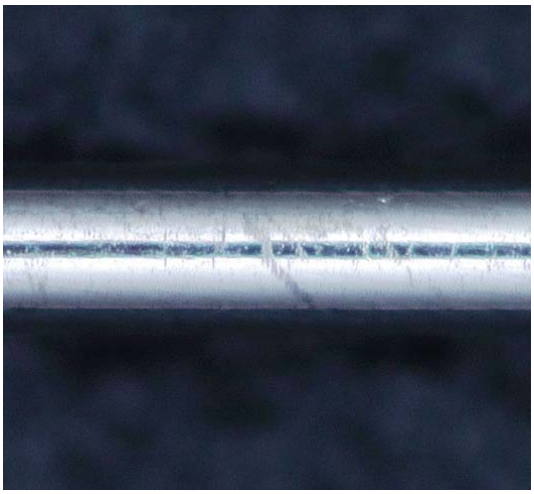

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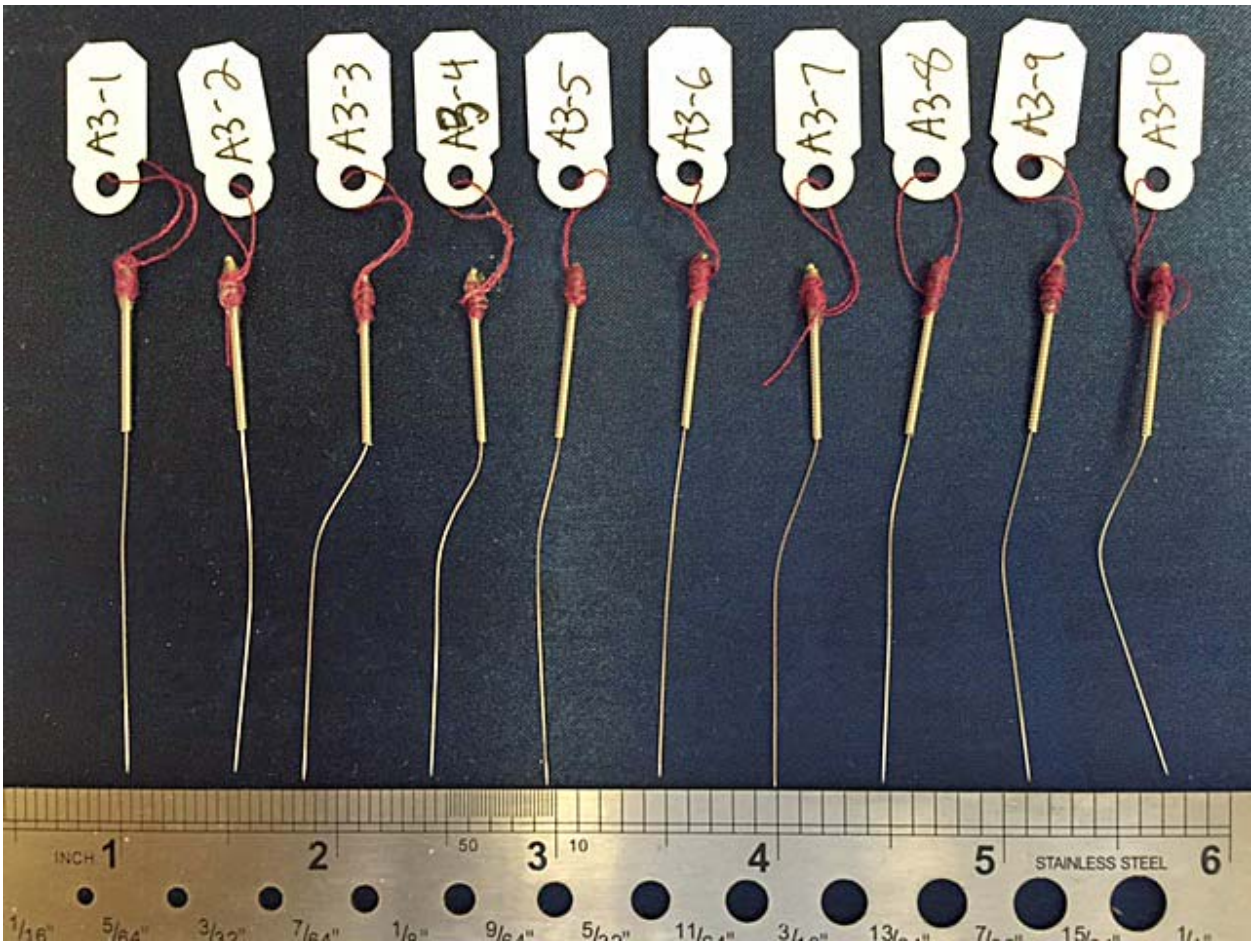

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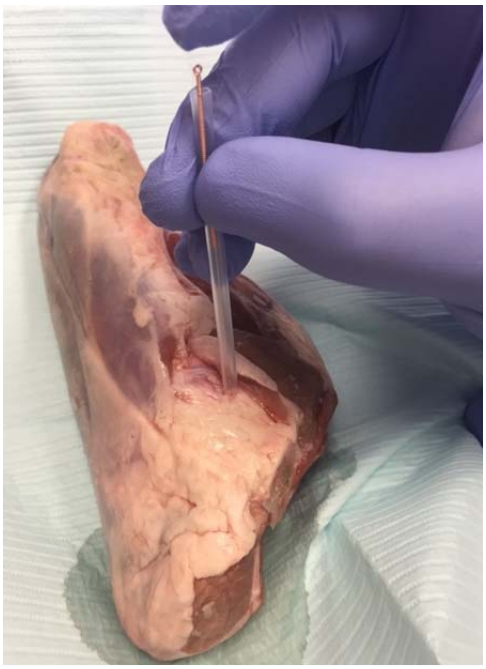

Photograph E

GUIDELINE VI: RESEARCH PROTOCOL APPROVAL

Walter Reed
National Military
Medical Center

07 December 2015

From: Director, Walter Reed National Military Medical Center, Bethesda, Maryland 20889
To: *Name – Dr. James Vick*

Subject: START LETTER - APPROVAL OF RESEARCH PROJECT #*500083-1, "Physical properties of acupuncture needles.*"

1. Congratulations! You have been granted approval to conduct your research project at Walter Reed National Military Medical Center, Bethesda (WRNMMC).

2. Your research protocol was approved after administrative, scientific, and ethical review by the Department of Research Programs (DRP) and the Determinations Officer. Other requirements such as agreements and committee requirements have been met, waived by the DRP chief, or determined unnecessary.

3. The Determinations Official has determined that this project does not meet the definition of human subject research under the purview of the IRB according to 32 CFR 219.

4. It is your responsibility as the Principal Investigator to have complete and accurate knowledge of what your protocol states you are allowed to do, and of any research agreements you have associated with your research.

5. You are reminded to provide all amendments, deviations, internal adverse events, or any other pertinent information to DRP as a new package. Submit all proposed changes to the study for review and approval before initiating the changes.

6. All written publications, clinical or research related, including abstracts, manuscripts, case reports and book chapters (e.g. reports of WRNMMC approved clinical investigation or research conducted by WRNMMC-assigned personnel; reports involving WRNMMC patients; reports citing WRNMMC in the title or byline) reflecting the WRNMMC affiliation must be submitted to WRNMMC publication clearance committee .

7. Please do not hesitate to contact the Determinations Official for assistance or the undersigned at (301) 400-1239 or peter.j.weina.mil@mail.mil with questions or concerns.

WEINA.PETER.JOSEPH.1099609385
Digitally signed by WEINA.PETER.JOSEPH.1099609385
DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USA, cn=WEINA.PETER.JOSEPH.1099609385
Date: 2015.12.07 15:27:30 -05'00'

PETER J. WEINA
COLONEL, MEDICAL CORPS, U.S. ARMY
CHIEF, DEPARTMENT OF RESEARCH PROGRAMS

1

DEPARTMENT OF THE NAVY
NAVY MEDICINE PROFESSIONAL DEVELOPMENT CENTER
8955 WOOD ROAD
BETHESDA, MARYLAND 20889-5628

IN REPLY REFER TO:
3900
Ser 00/1060
30 DEC 15

From: Commanding Officer, Navy Medicine Professional Development Center
To: LCDR James Vick, DC, USN

Subj: AUTHORITY TO BEGIN RESEARCH PROTOCOL #500083-1

Ref: (a) WRNMMC DRP Determinations Review of 500083-1
(b) SECNAVINST 3900.39 series

1. After review of reference (a), you are approved to begin research determined to not involve human subjects, as Principal Investigator under the protocol entitled "Physical Properties of Acupuncture Needles." This authority to begin research also extends to the Associate Investigator (s) for this project case file as approved by WRNMMC DRP.

2. In carrying out this research project, you will:

a. Conduct research according to the approved research policies and protocols contained in references (a) and (b).

b. Contact the NMPDC Human Research Protection Program Point of Contact, CDR Kenneth Green, for:

(1) Continuing reviews;

(2) Amendments to research protocol;

(3) Unanticipated problems, serious adverse events, protocol deviations, subject complaints;

(4) Final reports.

3. My point of contact, CDR Kenneth Green, may be reached at COMM 301-319-4837 or at kenneth.p.green2.mil@mail.mil.

P. M. SANCHEZ

Copy to:
File
Dean, NPDS
Department Head, NPDS Research
WRNMMC DRP Protocol Record